



# General

# Guideline Title

ACR Appropriateness Criteria® jaundice.

# Bibliographic Source(s)

Lalani T, Couto CA, Rosen MP, Baker ME, Blake MA, Cash BD, Fidler JL, Greene FL, Hindman NM, Katz DS, Kaur H, Miller FH, Qayyum A, Small WC, Sudakoff GS, Yaghmai V, Yarmish GM, Yee J. ACR Appropriateness Criteria® jaundice. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 9 p. [43 references]

#### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Foley WD, Bree RL, Rosen MP, Gay SB, Grant TH, Heiken JP, Huprich JE, Lalani T, Miller FH, Sudakoff GS, Greene FL, Rockey DC, Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® jaundice. [online publication]. Reston (VA): American College of Radiology (ACR); 2008. 7 p. [27 references]

# Recommendations

# Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Jaundice

<u>Variant 1</u>: Acute abdominal pain; at least one of the following: fever, history of biliary surgery, known cholelithiasis.

Radiologic Procedure	Rating	Comments	RRL*
US abdomen	9	To evaluate bile ducts and/or gallbladder	О
CT abdomen without and with contrast	8	Noncontrast in addition to contrast enhanced images only useful if stones are calcified and there is a suspicion of CBD stones.	
Rating Sealer Walls Controlly not appropriate	e;&,5,6 May be appropriate;	7.8. Onleasual planner prinate ing is useful in acute setting.	*Relative Radiation

Radiologic Procedure	Rating	Comments	RRL*
MRI abdomen without and with contrast with MRCP	8	Use of contrast in acute setting in addition to MRCP helps for cholangitis. See statement regarding contrast in text under "Anticipated Exceptions."	О
CT abdomen without contrast	6	Only useful if stones are calcified and there is a question of CBD stones.	
MRI abdomen without contrast with MRCP	6	If GFR precludes contrast.	О
ERCP	4	If there is high suspicion of CBD stones, some would advocate doing ERCP initially.	
US abdomen endoscopic	4		О
Rating Scale: 1,2,3 Usually not appropri	ate; 4,5,6 May be appropriate	; 7,8,9 Usually appropriate	*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 2</u>: Painless; one or more of the following: weight loss, fatigue, anorexia, duration of symptoms greater than 3 months. Patient otherwise healthy.

Radiologic Procedure	Rating	Comments	RRL*
CT abdomen with contrast	8	Biphasic arterial and portal venous phase may be useful and provides greater dose reduction than CT without and with contrast. If there is high pretest probability of obstruction due to malignancy, can be alternative to US.	
US abdomen	8	To evaluate bile ducts and/or gallbladder. May be the first-line test to evaluate for obstruction.	O
MRI abdomen without and with contrast with MRCP	8	If there is high pretest probability of obstruction due to malignancy, can be alternative to US and may provide roadmap for subsequent therapeutic intervention. See statement regarding contrast in text under "Anticipated Exceptions."	O
CT abdomen without and with contrast	7		
MRI abdomen without contrast with MRCP	7	If GFR precludes contrast.	О
ERCP	6	Not as an initial test. Would do imaging study first.	
Rating Graden Willfold wally aget appropris	ate; \$1,5,6 May be appropriate;	7. May the to appropriate dilated duct when GFR is low and patient is not able to have MRI.	*Relative Radiation Level

Radiologic Procedure US abdomen endoscopic	Rating 5	Comments May be appropriate as a therapeutic and diagnostic intervention for mass at the ampulla and periampullary region and may further staging.	RRL*
Rating Scale: 1,2,3 Usually not appropriat	e; 4,5,6 May be appropriate;	7,8,9 Usually appropriate	*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 3</u>: Clinical condition and laboratory examination makes mechanical obstruction unlikely.

Radiologic Procedure	Rating	Comments	RRL*
US abdomen	8	To evaluate liver for echogenicity, nodularity, stigmata of cirrhosis. Initial test.	
MRI abdomen without and with contrast with MRCP	8	If US is equivocal or does not answer the clinical question. Excludes biliary source of jaundice. Can visualize contour of liver, assess for liver iron and fat. Additional CE images may enable characterization of mass in cirrhotic livers. See statement regarding contrast in text under "Anticipated Exceptions."	
CT abdomen with contrast	7	Multiphase liver.	
MRI abdomen without contrast with MRCP	6	Excludes biliary source of jaundice. Can visualize contour of liver, assess for liver iron and fat.	О
CT abdomen without and with contrast	6	Noncontrast CT can help to confirm fatty liver in cases of NAFLD; contrast-enhanced multiphase CT can enable lesion characterization in cirrhotic livers.	
CT abdomen without contrast	5	Useful for assessing liver contour and NAFLD but does not exclude lesions.	
ERCP	3	Not as an initial test. Would do imaging study first.	
US abdomen endoscopic	3	May be useful only if imaging study does not yield a diagnosis.	О
Rating Scale: 1,2,3 Usually not appropria	te; 4,5,6 May be appropria	te; 7,8,9 Usually appropriate	*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Background/Introduction

One of the difficulties in determining a rational imaging strategy to evaluate jaundiced patients stems from the fact that jaundice is a clinical finding, not a single disease entity. The causes of nonhemolytic jaundice can be divided into two distinct categories: intrahepatic biliary stasis (hepatocellular jaundice) and mechanical biliary obstruction.

Because imaging plays little useful role in the evaluation of intrahepatic biliary stasis, the first task of the clinician caring for the jaundiced patient is to determine if jaundice is caused by bile duct obstruction. Several studies have shown that this distinction can be made in approximately 85% of patients using only clinical findings (age, nutritional status, pain, systemic symptoms, stigmata of liver disease, palpable liver or gallbladder) and simple biochemical tests. Patients with a high pretest probability of nonobstructive jaundice usually have either diffuse hepatocellular disease (e.g., cirrhosis, hepatitis), or, more rarely, inability of the liver to handle a bilirubin load (e.g., hemolytic anemia), or a metabolic deficiency (Gilbert's disease). These patients need no imaging studies; biopsy is usually the next step as clinically indicated.

Obstructive jaundice is jaundice resulting from obstruction to the flow of bile from the liver to the duodenum. In adults, extrahepatic (mechanical) obstruction accounts for 40% of patients presenting with jaundice as the primary symptom, and this likelihood increases with advancing age. The most common causes of obstructive jaundice in the United States are neoplasms of the pancreas, ampulla of Vater or biliary tract, choledocholithiasis, pancreatitis, and iatrogenic strictures of the biliary tree. Other less common causes include tumors metastatic to the biliary epithelium, sclerosing cholangitis, hepatic tumors adjacent to the hilum, perihepatic lymphadenopathy, and other causes of cholangitis.

#### Imaging Methods

The methods used in evaluating the jaundiced patient currently include ultrasound (US), computed tomography (CT), magnetic resonance cholangiopancreatography (MRCP), and endoscopic retrograde cholangiopancreatography (ERCP). These examinations are effective to varying degrees in assessing both the cause and the site of obstruction; ERCP also can relieve the obstruction in a significant portion of cases. Endoscopic US (EUS) can be used as an adjunct examination to ERCP in cases of common bile duct (CBD) obstruction and can be used to determine whether the obstruction is from mass or stone.

The literature is replete with articles confirming the usefulness of all of these methods, but comparative studies have rarely considered the effect of factors that may influence the validity of their conclusions. Among these factors are the prevalence of extrahepatic obstruction in the population studied, the various causes of obstruction (case mix) in the series (often a function of institutional bias), and the frequency of uninterpretable results or unsuccessful studies. These factors influence the apparent differences in efficacy. In designing appropriateness criteria, therefore, the guideline developers have chosen to consider strategies in terms of the pretest probability that jaundice is due to either mechanical obstruction or parenchymal liver disease.

It must be remembered that the results of any given imaging method strongly depend on the population studied and the expertise of the examiners. For this reason, local conditions and expertise should properly influence the method by which jaundiced patients are evaluated.

#### Radiographs

Radiographs rarely provide any information on the site or the cause of obstruction and have no place in the evaluation of the jaundiced patient.

#### Ultrasound

US is the least invasive and lowest cost imaging technique available for evaluating obstructive jaundice. US is used to determine the presence of obstructive jaundice by detecting dilated bile ducts, with sensitivity of 55% to 95% and specificity of 71% to 96%. False-negative studies are due to two factors: inability to see the extrahepatic biliary tree (often because of interposed bowel gas), and the absence of biliary dilation in the presence of obstruction. US is less effective than CT or MRCP for determining the site and the cause of obstruction.

#### Computed Tomography

CT is slightly more sensitive (74% to 96%) and specific (90% to 94%) than US in detecting biliary obstruction; in addition, the ability to determine the site and the cause of obstruction is greater with CT than with US. Recent articles claim that its sensitivity for obstruction is >90%, especially given the advent of multidetector CT (MDCT) and image reformations. CT is strongly recommended as the primary modality for evaluating patients with suspected malignant biliary obstruction, both for diagnosis and for staging. CT cholangiopancreatography generated by slab volume imaging with minimum-intensity projections (MinIp) and curved planar reformations may be useful for preintervention planning. Recent studies also examine the utility of CT for predicting tumor extension and potential resectability.

#### Magnetic Resonance Imaging

Magnetic resonance imaging (MRI) can demonstrate both the site and cause of biliary obstruction. MR cholangiography has been shown to be useful in depicting the three-dimensional anatomy of the biliary and pancreatic ducts. For detection of ductal calculi, MRCP is the most sensitive of

the noninvasive techniques. The use of MRCP may decrease the number of ERCP examinations obtained prior to elective cholecystectomy. More recent studies have recommended MRCP as the preferred test in patients with a high likelihood of choledocholithiasis. MRCP is valuable in the clinical situation of failed ERCP and in patients with hilar biliary obstruction due to ductal tumor or periductal compression. MRCP is the test of choice in pregnant women with known or suspected pancreaticobiliary disease due to lack of nonionizing radiation.

#### Endoscopic Retrograde Cholangiopancreatography

ERCP is the most common invasive diagnostic biliary procedure and has evolved gradually from its initial role as a diagnostic tool. Due to significant advances in cross-sectional imaging, in particular the advent of MRCP, ERCP currently has an almost exclusively therapeutic role. Due to its inherent risks, costs, and invasive nature, ERCP should be indicated only for therapeutic reasons or when it can alter patient management. In addition, the procedure carries a potentially severe morbidity of up to 10%, most commonly pancreatitis, and a 0.4% mortality rate. These factors need to be weighed against the potential benefits of ERCP. The main indication for ERCP remains management of CBD stones, which can be cleared in 80%-95% of cases. Some also advocate ERCP in the management of severe acute biliary pancreatitis, along with cases of more mild disease complicated by one of the following: presence of gallstones plus high operative risk, absence of gallstones or prior cholecystectomy, or pregnancy. ERCP also remains the standard for stent placement in cases of obstructive jaundice. When deployed for distal CBD strictures, stenting via ERCP is successful in more than 90% of cases. Stent deployment can be more complicated in cases of hilar cholangiocarcinoma, when placement of more than one stent could be necessary to achieve adequate drainage of the biliary tree. There remains a limited role for diagnostic ERCP, essentially restricted to tissue sampling from biliary or pancreatic lesions, sphincter of Oddi manometry, and diagnostic pancreatoscopy or cholangioscopy.

#### Endoscopic Ultrasound

EUS, an adjunct procedure to ERCP, can be used to detect small distal biliary ductal calculi, for local staging of periampullary neoplasm, and for guided fine-needle aspiration (FNA) biopsy. The sensitivity, specificity, positive predicative value, and accuracies of EUS FNA biopsy for tumor are 84.6%, 100%, 100%, and 87.8%, respectively. Recent literature also supports the use of EUS as an adjunct in evaluating potential duct strictures as well as early-stage tumors in the nonicteric stage.

#### Clinical Categories

To determine the appropriateness of any imaging test, it is necessary to consider the general clinical category to which the patient belongs. The major categories are (1) high likelihood of mechanical obstruction; (2) low likelihood of mechanical obstruction; and (3) indeterminate. For situations in which the pre-imaging probability for obstruction is high, it is also appropriate to consider a second question: whether the obstruction is likely to be benign or malignant.

#### Variant 1: High Likelihood of Benign Biliary Obstruction

Patients in this category present with jaundice and acute abdominal pain. There may be a prior history of gallstones documented by US or of prior biliary surgery. US is a readily available and inexpensive method for detecting dilated intrahepatic bile ducts and the common hepatic duct at the hepatic hilum. Biliary ductal calculi are not detected with the same sensitivity as gallbladder calculi. In fact, the sensitivity for detection of CBD stones on US is 30%, as the subhepatic common duct may not be visible due to overlaying bowel gas. In addition, intrahepatic bile ducts may not be dilated in the early phase of acute obstruction or in patients with partial obstruction. Sensitivity of detection can be increased to 70%-86% by combining tissue harmonic imaging, elevated bilirubin, age >55 years, and CBD dilatation between 6-10 mm. Despite recognized limitations, US is recommended as the initial diagnostic test in patients with suspected calculus obstruction of the common duct.

In patients with acute biliary obstruction and suspected complicating conditions such as cholangitis, cholecystitis or pancreatitis not well evaluated by US, a preintravenous and postintravenous contrast-enhanced abdominal CT study is useful in defining the level of obstruction, likely cause, and coexistent complications. CT can be used to detect partially calcified biliary calculi, but is insensitive in detecting bilirubinate or cholesterol calculi. Isotropic data routinely obtained with current multislice technology can be reconstructed using narrow collimation, and smaller reconstruction intervals allow for better visualization of the calculi.

MRCP and ERCP are sensitive for detecting biliary ductal calculi. The use of MRCP will improve the therapeutic yield of ERCP; however, MRCP has diminishing sensitivity with decreasing stone size <6 mm. For these small stones EUS is most useful, as decreasing stone size does not hamper its performance, and complications with diagnostic EUS are rare.

Therapeutic endoscopic intervention including sphincterotomy may be curative, but it has associated morbidity of up to 10% due to risk of iatrogenic pancreatitis. In patients with previous gastroenteric anastomoses, MRCP is recommended as the technique of choice to evaluate the extrahepatic biliary ductal system.

In patients with suspected sclerosing cholangitis or biliary stricture, MRCP is the preferred imaging modality, avoiding the possibility of suppurative

cholangitis that may be induced by endoscopic catheter manipulation of an obstructed biliary system. MRCP findings may guide directed approaches such as ERCP with brushing, percutaneous transhepatic biliary stenting, or reconstructive surgery.

#### Variant 2: High Likelihood of Malignant Biliary Obstruction

Patients typically present with insidious development of jaundice and associated constitutional symptoms (weight loss, fatigue, etc.). Mechanical biliary obstruction can be confirmed by US. Malignant obstruction is most commonly due to pancreatic carcinoma but may be secondary to cholangiocarcinoma of either the proximal or distal duct or to periductal nodal compression.

64-slice MDCT using MinIp and multiplanar reconstructions (MPRs) shows excellent spatial resolution and accuracy for staging of biliary malignancies and helps differentiate benign from malignant strictures. Reported sensitivity, specificity, and accuracy are 95%, 93.35% and 88.5%, respectively. Important information in tumor staging includes tumoral involvement of the biliary confluence, invasion of the superior mesenteric and portal vein, peripancreatic tumor extension, regional adenopathy, and hepatic metastases. Biphasic CT of the abdomen with pancreatic and portal venous phase imaging through the liver, biliary tree, and pancreas is the standard protocol for staging of pancreaticobiliary malignancies. However, improved z-axis resolution, isotropic data sets, and improved multiplanar capability must be balanced with the increased radiation dose to the patient in the acquisition of multiple phases.

MRI and MRCP are also accurate in tumor detection and staging. For example, accuracy rates for MRI with MRCP and MDCT are similar: 90.7% versus 85.1% for bilateral secondary biliary confluence involvement and 87% for both in detecting intrapancreatic CBD involvement in bile duct malignancies.

ERCP is invasive and more expensive than CT or MRI and has equivalent sensitivity in tumor detection, particularly for ampullary carcinoma, but does not provide staging information for operability. Tissue diagnosis can be obtained by endoscopically directed brushing or guided US with FNA. Additionally, in patients with suspected malignant biliary obstruction and negative or equivocal CT or MRI examinations, ERCP with EUS may provide an imaging and cytologic diagnosis (FNA).

Endoscopic or percutaneous transhepatic biliary drainage is appropriate for patients who are not candidates for surgery and may even be useful in operative candidates for whom there is a delay to definitive surgical resection. Standard ERCP is sufficient in 90% to 95% of patients who require biliary decompression. Factors that contribute to ERCP failure include gastric outlet or duodenal obstruction due to tumor invasion, or altered anatomy from diverticula or prior surgery. Percutaneous transhepatic cholangiography (PTC) can be used for decompression but requires external drainage, which can be a source of biliary infection. EUS-guided biliary drainage offers less morbidity as no external drainage is required, and it is increasingly used as a replacement for PTC. In patients without pancreaticobiliary malignancy, periductal nodal disease can result in obstruction. Here, a diagnosis of lymphoma or metastatic adenopathy can be obtained with either image-guided biopsy or EUS.

#### Variant 3: Low Likelihood of Mechanical Biliary Obstruction

In situations where the pre-test probability of mechanical biliary obstruction is low, either US or MRCP can be used as first-line imaging techniques because of their availability, absence of ionizing radiation, and low complication rates. US is less expensive though less definitive, especially for distal CBD and for ampullary and pancreatic visualization.

When most of the abdominal organs need to be assessed, either CT or MRI can be used, though CT more reliably displays all abdominal anatomy. When CT evaluation is compromised (e.g., in patients unable to receive iodinated intravenous contrast material), the combination of MRI and MRCP is a reliable alternative to exclude parenchymal cause for jaundice and to confirm that the pancreaticobiliary system is unobstructed. When imaging does not yield a cause for jaundice (i.e., there is no obstruction and no parenchymal process to explain jaundice), liver dysfunction or infiltrative process must be excluded, and liver biopsy will be the most effective next step in diagnosis.

#### Special Considerations

The above situations address the initial workup of the jaundiced patient. It is assumed that once the initial workup has been performed and etiology of the obstruction ascertained, those patients with a mechanical obstruction will be triaged into endoscopic or percutaneous biliary drainage to alleviate the obstruction (see the National Guideline Clearinghouse [NGC] summary ACR Appropriateness Criteria® percutaneous biliary drainage in benign and malignant biliary obstruction). For those patients without mechanical obstruction, biopsy will help to elucidate the underlying process, and subsequent diagnosis will dictate follow-up.

#### Summary

The diagnostic approach for adults presenting with jaundice depends to a large extent on: clinical symptoms of pain, prior history of gallstones, acuity and/or duration of jaundice, and associated symptoms.

The first objective of imaging is to decide whether there is mechanical obstruction. US as a first-line modality helps to confirm bile duct dilatation if present to assess for the presence or absence of stones, and to direct the second-line test.

- If a mechanical cause is suspected and there is associated right upper quadrant pain and a history of stones, MRI and MRCP may be the second modality performed.
- If there is mechanical obstruction but no stone disease and high suspicion of malignancy, then biphasic pancreatic CT with thin reconstructions can help define the point of obstruction, assess for resectability, and stage for metastatic disease.
- If no mechanical cause for jaundice is identified by the first-line modality of US, it is important to exclude infiltrative disease before
  performing invasive testing such as liver biopsy. Here, the superior tissue characterization offered by MRI may help further the diagnosis and
  may help direct biopsy.

The availability of each modality and the expertise with which it is offered, institutional and referring physician preference, inherent patient characteristics (renal insufficiency, claustrophobia, implanted devices, ability to lay still), and radiation dose will also affect the choice. CT is readily available even in small rural hospitals but comes with inherent dose to patient. MRI may not be as readily available and may be difficult to obtain emergently, but it can be an alternative to CT when radiation dose is a consideration, such as in a younger or pregnant patient. All these modalities will have similar sensitivity, specificity and accuracy for depicting malignant disease, though MRI will be slightly superior for stone disease.

#### Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m²), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m². For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

#### Abbreviations

- CBD, common bile duct
- CE, contrast-enhanced
- CT, computed tomography
- ERCP, endoscopic retrograde cholangiopancreatography
- GFR, glomerular filtration rate
- MRCP, magnetic resonance cholangiopancreatography
- MRI, magnetic resonance imaging
- NAFLD, nonalcoholic fatty liver disease
- US, ultrasound

#### Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
О	0 mSv	0 mSv
	<0.1 mSv	<0.03 mSv
	0.1-1 mSv	0.03-0.3 mSv
	1-10 mSv	0.3-3 mSv
	10-30 mSv	3-10 mSv
	30-100 mSv	10-30 mSv

<sup>\*</sup>RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."

# Algorithms were not developed from criteria guidelines. Scope Disease/Condition(s) Jaundice **Guideline Category** Diagnosis Evaluation Clinical Specialty Family Practice Gastroenterology Internal Medicine Nuclear Medicine Oncology Radiology **Intended Users** Health Plans Hospitals Managed Care Organizations Physicians Utilization Management Guideline Objective(s) To evaluate the appropriateness of initial radiologic examinations for patients with jaundice

# Target Population

Clinical Algorithm(s)

Patients with jaundice

# Interventions and Practices Considered

1. Ultrasound (US)

- Abdomen
- Abdomen endoscopic
- 2. Computed tomography (CT) abdomen
  - With contrast
  - Without contrast
  - Without and with contrast
- 3. Magnetic resonance imaging (MRI) abdomen
  - Without contrast with magnetic resonance cholangiopancreatography (MRCP)
  - Without and with contrast with MRCP
- 4. Endoscopic retrograde cholangiopancreatography (ERCP)

# Major Outcomes Considered

Utility of radiologic examinations in differential diagnosis

# Methodology

#### Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

# Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

- 1. Articles that have abstracts available and are concerned with humans.
- 2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 5 years unless the topic author provides other instructions.
- 3. May restrict the search to Adults only or Pediatrics only.
- 4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

#### Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

# Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

# Rating Scheme for the Strength of the Evidence

Strength of Evidence Key

- Category 1 The conclusions of the study are valid and strongly supported by study design, analysis and results.
- Category 2 The conclusions of the study are likely valid, but study design does not permit certainty.
- Category 3 The conclusions of the study may be valid but the evidence supporting the conclusions is inconclusive or equivocal.
- Category 4 The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

# Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

# Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence for all articles included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member forms his/her own opinion based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

#### Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

# Description of Methods Used to Formulate the Recommendations

## Modified Delphi Technique

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distributes surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The ratings are a scale between 1 and 9, which is further divided into three categories: 1, 2, or 3 is defined as "usually not appropriate"; 4, 5, or 6 is defined as "may be appropriate"; and 7, 8, or 9 is defined as "usually appropriate." Each panel member assigns one rating for each procedure per survey round. The surveys are collected and the results are tabulated, de-identified and redistributed after each round. A maximum of three rounds are conducted. The modified Delphi technique enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive bias from fellow panelists in a simple, standardized and economical process.

Consensus among the panel members must be achieved to determine the final rating for each procedure. Consensus is defined as eighty percent (80%) agreement within a rating category. The final rating is determined by the median of all the ratings once consensus has been reached. Up to three rating rounds are conducted to achieve consensus.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is accepted as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

# Rating Scheme for the Strength of the Recommendations

Not applicable

# Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### Method of Guideline Validation

Internal Peer Review

# Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

# Evidence Supporting the Recommendations

# Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

# Benefits/Harms of Implementing the Guideline Recommendations

#### Potential Benefits

Selection of appropriate radiologic imaging procedures for evaluation of patients with jaundice

## Potential Harms

- False-negative results of imaging studies.
- Endoscopic retrograde cholangiopancreatography (ERCP) carries a potentially severe morbidity of up to 10%, most commonly pancreatitis, and a 0.4% mortality rate. Due to its inherent risks, costs, and invasive nature, ERCP should be indicated only for therapeutic reasons or when it can alter patient management.

#### Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

#### Gadolinium-based Contrast Agents

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based

contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m²), and almost never in other patients. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m². For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

# **Qualifying Statements**

# **Qualifying Statements**

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

# Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

**IOM Domain** 

Effectiveness

# Identifying Information and Availability

Bibliographic Source(s)

Lalani T, Couto CA, Rosen MP, Baker ME, Blake MA, Cash BD, Fidler JL, Greene FL, Hindman NM, Katz DS, Kaur H, Miller FH, Qayyum A, Small WC, Sudakoff GS, Yaghmai V, Yarmish GM, Yee J. ACR Appropriateness Criteria® jaundice. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 9 p. [43 references]

# Adaptation

Not applicable: The guideline was not adapted from another source.

#### Date Released

1996 (revised 2012)

# Guideline Developer(s)

American College of Radiology - Medical Specialty Society

# Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

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Committee on Appropriateness Criteria, Expert Panel on Gastrointestinal Imaging

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#### Financial Disclosures/Conflicts of Interest

Not stated

## Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Foley WD, Bree RL, Rosen MP, Gay SB, Grant TH, Heiken JP, Huprich JE, Lalani T, Miller FH, Sudakoff GS, Greene FL, Rockey DC, Expert Panel on Gastrointestinal Imaging. ACR Appropriateness Criteria® jaundice. [online publication]. Reston (VA): American College of Radiology (ACR); 2008. 7 p. [27 references]

# Guideline Availability

Electronic copies: Available from the American College of Radiology (ACR) Web site
Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900
Availability of Companion Documents
The following are available:
<ul> <li>ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site</li> <li>ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in Portable Document Format (PDF) from the ACR Web site</li> <li>ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in PDF from the ACR Web site</li> <li>ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the ACR Web site</li> <li>ACR Appropriateness Criteria®. Manual on contrast media. Reston (VA): American College of Radiology; 92 p. Electronic copies: Available in PDF from the ACR Web site</li> <li>ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in PDF from the ACR Web site</li> <li>ACR Appropriateness Criteria® jaundice. Evidence table. Reston (VA): American College of Radiology; 20 p. Electronic copies: Available from the ACR Web site</li> <li>ACR Appropriateness Criteria® jaundice. Evidence table. Reston (VA): American College of Radiology; 20 p. Electronic copies: Available from the ACR Web site</li> </ul>
Patient Resources
None available
NGC Status
This summary was completed by ECRI on March 19, 2001. The information was verified by the guideline developer on March 29, 2001. This NGC summary was updated by ECRI Institute on June 23, 2009. This summary was updated by ECRI Institute on January 13, 2011 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This NGC summary was updated by ECRI Institute on September 11, 2012.
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